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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,350	11/30/2001	Peter P. Roller	214683	5514
23460	7590	01/28/2005	EXAMINER	
LEYDIG VOIT & MAYER, LTD TWO PRUDENTIAL PLAZA, SUITE 4900 180 NORTH STETSON AVENUE CHICAGO, IL 60601-6780			CHANDRA, GYAN	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 01/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/998,350

**Applicant(s)**

ROLLER ET AL.

**Examiner**

Gyan Chandra

**Art Unit**

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 5, 6 and 9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-6, and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### Status of Application, Amendments, And/Or Claims

Claims 3-4, 7-8, and 10-22 are canceled.

Claims 1,2, 5-6, and 9 are pending and are under consideration.

### *Specification*

The amendment to the specification, after the title of the instant application so to include " This application claims benefit of PCT Application US00/15201 filed on 06/02/2000 and Provisional Application No. 60/137187, filed on 06/02/1999." has been entered.

### *Claim Rejections under - 35 USC § 112, 1<sup>st</sup> paragraph (Enablement)*

The rejection of claims 1, 2, 5, 8-11, 17, 25-27, 36, 37, 39, 50, 51, 53, 77 and 78 under 35 USC § 112, first paragraph, as lacking enablement, is maintained.

Applicants argue that claim 1 and the depending claims 2, 5,6, and 9 are directed to a compound of SEQ ID NO: 1, and not a method of using the compound of SEQ ID NO: 1.

The statute 35 U.S.C. 112 requires that:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Applicants' disclosure provides guidance as to how to prepare a compound with SEQ ID NO: 1, and provides guidance to one skilled in the art to add "L" moiety as a Sulfoxide (SO) and a signal peptide as a carrier agent (examples 4 and 12). Applicants contemplate administering the cyclic peptide with SEQ ID NO: 1 to prevent breast cancer. However, the specification does not provide any detailed guidance on how to use the invention to prevent cancer, in particular breast cancer the only disclosed use of compound taught in the specification. At best, Applicants show an *in vitro* binding assay in an established cell line. Applicants' example of the cyclic peptide and its IC 50 from MDA-MB-453 cell line for its intended use is highly unpredictable for the reason set forth in the previous office action on 09/03/2004. Given the general teachings in the art of the unpredictability of *in vivo* administration of peptide as therapeutic, enablement must be provided in the instant disclosure. The specification lacks any teachings on how one skilled in the art can use the cyclic peptide of SEQ ID NO: 1 as a therapeutic for administering in a subject with breast cancer or other diseases.

Applicants' argument that the elements of claim 1 referring to certain *in vivo* properties of the compound of SEQ ID NO: 1 are merely inherent properties of any compound encompassed by the generic amino acid sequence of SEQ ID NO: 1, has been fully considered, but is not deemed persuasive because the instant specification does not enable the compound of SEQ ID NO: 1 for the solely disclosed use of the compound which is preventing cancer, in particular breast cancer (page 7, line27-29 of the specification). For the reasons set forth above and in the previous rejection, the enablement rejection to claims is maintained.

***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gyan Chandra  
AU 1646  
19 January 2005

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